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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
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| 10/756,851 | 01/14/2004 | Darin G. Schaeffer | 8627-368 (DN-1484) | 3412 |
| 7590 08/14/2007 Brinks Hofer Gilson & Lione P.O. Box 10395 Chicago, IL 60610 | | | EXAMINER NEAL, TIMOTHY J | |
| | | | ART UNIT 3731 | PAPER NUMBER |
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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary

Application No.

10/756,851

Applicant(s)

SCHAEFFER ET AL.

Examiner

Timothy J. Neal

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 14 May 2007.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-41 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-41 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

This action is in response to the amendments filed on 5/14/2007. The Examiner acknowledges that the Affidavit filed on 5/14/2007 has been received and will be addressed in the Response to Arguments section of the action.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 1-5, 8-10, 12-14, 18, 22-26, 29-31, 33-35, and 39 are rejected under 35 U.S.C. 103(a) as being unpatentable over Applicant's disclosure of admitted prior art.

The Applicant has disclosed in Figures 1-8 labeled Prior Art: a sheath (Items 30, 40, and 50) with a flange (Item 36 and 48) and beveled portion (Item 34) and a slot through the length of the sheath (Item 44). Embodiment 2 (Item 40) of the prior art is not made of a flexible material. Embodiment 3 is made of a flexible material. Plastic is an obvious choice for a flexible material. The addition of a slot to facilitate the entry of the instrument into the sheath is also taught by embodiment 2 (Item 40). Embodiment 1 includes a beveled end. The combination of embodiment 1 (Item 30) and embodiment 2 (Item 40) would result in the slot being disposed at the heel of the bevel. The Examiner considers the placement of the slot at any desirable location to be within the

purview of one having ordinary skill in the art. Locating the slot at the heel of the bevel would provide a leading tip that would reduce the likelihood of the sheath opening or peeling back upon entry into the valve. Beveled ends are known in the art of trocars and other introducers to facilitate placement in the body. One having ordinary skill would apply this beveled end to the flexible material of embodiment 3 to solve to entry problems. Therefore, it would have been obvious to a person having ordinary skill in the art at the time the invention was made to modify the prior art embodiments as disclosed by the Applicant to include the plastic flexible material, slot, and beveled end into one embodiment. Such modifications would improve the coverage of the instrument when in the sheath (flexible material), allow the introducer to be removed from the catheter (slot), and facilitate entry into the valve (beveled end).

The Examiner considers substantially closing the slot (Item 44) to be within the purview of one having ordinary skill in the art. This modification would more securely hold the instrument in place during insertion. Furthermore, the Examiner is providing an example of a device for holding a catheter with both the open and closed configurations claimed to show that these configurations are within the purview of one having ordinary skill in the art. McIvor et al. (US 6,213,988) teaches a clip of similar cross section to the sheath containing a closed configuration (Fig 10A) and an open configuration (Fig 10B). Therefore, it would have been obvious to a person having ordinary skill in the art to modify the Applicant's admitted prior art slot to include a closed state. Such a modification provides the advantage of locking the device inside the sheath so that it will not be accidentally displaced during insertion.

Claims 6, 7, 11, 15-17, 19, 20, 27, 28, 32, 36-38, 40, and 41 are rejected under 35 U.S.C. 103(a) as being unpatentable over Applicant's disclosure of admitted prior art in view of Stephens '586 or McIvor (US 6,213,988).

The disclosed prior art discloses the invention substantially as claimed as stated above. The prior art does not explicitly disclose a hinge. Stephens teaches a hinge (112) with a thinner portion. McIvor also teaches a hinge with a thinner portion (Figure 10A). Therefore, it would have been obvious to a person having ordinary skill in the art at the time the invention was made to modify the admitted prior art to include a hinge as taught by Stephens or McIvor since such a modification would improve the introducer's ability to open and close.

Response to Arguments

Applicant's arguments with respect to claims 1-41 have been considered but are moot in view of the new ground(s) of rejection.

The Examiner has taken a closer look at the three embodiments disclosed as prior art in figures 1 through 8. It appears to the Examiner that the Applicant has taken the best features of the three embodiments and combined them into one device. The first embodiment (figures 3 and 4) includes a beveled distal end. The second embodiment (figures 5 and 6) includes the slot. The third embodiment (figures 7 and 8) includes the flexible material. The beveled distal end of the first embodiment eases the introduction of the device into the valve, a problem with the third embodiment. The

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second embodiment includes a slot so the introducer can be removed once the catheter has been inserted, a problem with the first and third embodiments. The third embodiment includes the flexible material. One having ordinary skill in the art would recognize the ability of a flexible material to open and close, thus solving the sizing problems of the second embodiment. Trocars and other introducers widely include a beveled end to ease the insertion of the device into the body. A person of ordinary skill would know this and be able to apply this to the flexible material of the third embodiment to ease the insertion of the introducer through the valve. Thus the claimed invention is essentially the combination of the known prior art devices in a predictable manner with the advantages stated above to overcome the known deficiencies in the prior art devices.

The Examiner has reviewed the opinion of Mr. Schaeffer. Mr. Schaeffer points to the deficiencies of Stephens and why the combination of Stephens with the admitted prior does not read on the claimed invention. The Examiner has removed Stephens as a teaching reference for the flexible material because the third embodiment of the admitted prior art includes a flexible material that is at least strong enough to be used with the hemostatic valve. The Examiner also notes that the claims do not positively recite a hemostatic valve. The language is merely functional and given little to no patentable weight.

The response above is considered to sufficiently address all of the Applicant's arguments.

Conclusion

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the date of this final action.


Any inquiry concerning this communication or earlier communications from the examiner should be directed to Timothy J. Neal whose telephone number is (571) 272-0625. The examiner can normally be reached on M-F 9:00-5:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Anhtuan Nguyen can be reached on (571) 272-4963. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

TJN



LOAN H. THANH
PRIMARY EXAMINER